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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,253	08/15/2001	James Baber Rowe	01-179	7071
20306	7590	10/22/2004	EXAMINER	
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP 300 S. WACKER DRIVE 32ND FLOOR CHICAGO, IL 60606			PORTNER, VIRGINIA ALLEN	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,253

Applicant(s)

ROWE ET AL.

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 8-12, 15-23 and 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-3, 5, 8-12, 15-23, 52 is/are rejected.
- 7) ☐ Claim(s) 3, 8-12, 15-23 and 52 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 4,6-7,13-14, 24-51 have been canceled.

Claims 1-3, 5, 9, 10, 11,2021-23and 52 have been amended; therefore any claims which depend therefrom also recite a new combination of claim limitations.

Claims 1-3,5,8-12,15-23 and 52 are pending.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections Withdrawn

1. All rejections over canceled claims are automatically withdrawn.

2. The Obvious Type Double Patenting rejection has been obviated through submission of an effective Terminal Disclaimer.

3. Claims 2-3,10, 11, 22,23 and 52 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for various compositions that comprise the recited bacteria, does not reasonably provide enablement for the specific isolate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use novel strains with unobvious characteristics the invention commensurate in scope with these claims.

4. Specifically rejections as follows under 35 USC 112, second paragraph, in light of amendments, cancellation of claims and cancellation of claim limitations:

a. Claims 20-23 recite the phrase "an active agent". The activity of the active agent is not defined, by any specific structure or known biological function. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

b. Claims 27-29 recite the term "bacteria"; this term lacks antecedent basis in claim 25 which recites the term microorganism.

c. Claim 25 recites the term "active agent" and depends from claim 19 which recites the limitation "microorganism"; there is insufficient antecedent basis for this limitation in claim 19; claim 25 broadens the scope of claim 19 by redefining what is administered.

d. Claim 26 defines the antibiotics to be active against gram positive microorganisms, and indirectly depends from claims 1 and 10 which also recite gram negative microorganisms. It is unclear how the active agent of claim 26 corresponds to the recited gram negative bacteria in the compositions set forth in claims 1 and 10. How claim 26 is further limiting of the genus of gram negative compositions defined in claims 1 and 10 is unclear.

e. Claim 27 defines the active agent to interact with gram negative bacteria and indirectly depends from claims 1 and 10 which also recite gram positive microorganisms. It is unclear how the active agent of claim 27 corresponds to the recited gram positive bacteria in the compositions set forth in claims 1 and 10. How claim 27 is further limiting of the genus of gram positive compositions defined in claims 1 and 10 is unclear.

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f. Claim 29 recites the phrase "indirectly active against lactic acid producing gram negative bacteria" and indirectly depends from claim 19 which recites compositions of gram positive bacteria through depends upon claims 1 and 10 which recite Streptococcus. It is unclear how the active agent of claim 29 corresponds to the recited gram positive bacteria in the compositions set forth in claims 1 and 10. How claim 29 is further limiting of the genus of gram positive compositions defined in claims 1 and 10 is unclear.

g. Claim 32 recites the phrase "yeast and mycelial preparations"; these terms lack antecedent basis in claim 31 from which claim 32 depends. This rejection could be obviated by amending the claim to recite --further comprises--.

5. Claims 1-18, 25-32 and 52 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as they no longer recite the intended use of preventing lactic acidosis and are compositions that comprise lactic acid producing bacteria.

6. Claims 1-3, 5, 8, 18, 21-22-23, 25-32 and 52 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reciting the phrase "fragment or fragments" as this phrase has been deleted from these claims.

7. Claims 1-23, 25-32 and 52 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reciting the term "like" has been obviated through deletion of this term from the claims.

8. Claims 1-4, 7 and 9-12 rejected under 35 U.S.C. 102(b) as being anticipated by Hayashi et al (US Pat. 4,906,612) as evidenced by US Pat. 6,429,006 in light of the cancellation and amendment of the claims to no longer read on isolated antigens of a lactic acid bacteria, and removal of the term "like" from the claims.

9. Claims 21-23 rejected under 35 U.S.C. 102(b) as being anticipated by Leedle et al (US Pat 5,380,525), in light of the amendment of claim 21 to no longer recite the phrase "active agent" and the compositions are no longer disclosed in Leedle et al; claims 22-23 depend from claim 21 and therefore no longer recite the term "active agent".

Objections/Rejections Maintained

10. Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 12 is not only directed to microorganisms, but to purified antigens that are not microorganisms that can produce lactic acid. The objection is maintained for reasons of record.

11. Claims 2-3, 10, 11, 22, 23 and 52 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for various compositions that comprise the recited bacteria, does not reasonably provide enablement for the specific isolate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use novel strains with unobvious characteristics the invention commensurate in scope with these claims, in light that the statement that restrictions to access would be removed upon granting of a patent has not made, either in the instant Specification, nor in Applicant's Remarks.

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12. Claims 9-12,15-17,19-20 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for whole living compositions of microorganisms that reduce lactic acidosis, specific agents that reduce lactic acidosis conditions, and specific immunogens that will induce an immune response that will specifically inhibit the production of lactic acidosis does not reasonably provide enablement for any fragment or fragments of any of the recited microorganisms to function as a vaccine or pharmaceutical component of a pharmaceutical composition administered to an animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

13. Claims 19-23 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reciting the phrase "prophylaxis of lactic acidosis in a vertebrate" when the administered composition comprises lactic acid producing bacteria defined by the compositions of claim 1 and claim 10, for reasons of record in paper number 12204, paragraph 22.

14. Claims 9-12,15-17,19-20 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reciting embodiments that encompass "fragment or fragments" of microorganisms, in light of claim 12 still reciting a combination of claim limitations that read on the phrase "fragment or fragments" through the recitation of "crude antigen mixture or purified antigen or antigens from the microorganism.", claim 12 depending from independent claim 9, the scope of claim 9 including the species recited in claim 12 and all claims dependent from claim 9.

15. Claims 1-3,9-11,23 and 52 are rejected, as previously applied to claims 3, 11, 23 and 52, under 35 U.S.C. 112, second paragraph, for setting apart claim limitations in brackets, for reasons of record in paper number 12204, paragraph 25, as all of these claims now recite brackets. This rejection could be obviated through removal of the bracketed terms to positively recite the claim limitations in the claims, rather than reciting examples of the invention set apart by brackets.

16. Claim 1,8-9,12, 16, 18, 19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Leer et al for reasons of record in paper number 12204, paragraph 37, and responses to arguments set forth below.

17. Claims 1-2,8-10, 12, 15-22 rejected under 35 U.S.C. 102(b) as being anticipated by WO99/00136, publication date January 7, 1999, for reasons of record in paper number 12204, paragraph 38.

Response to Arguments

18. The objection of claim 12 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is traversed on the grounds that claim 9 has been amended, and claim 12 is asserted to be "within the scope of claim 9".

19. It is the position of the examiner that claim 9 encompasses "dead cells"; this term does not define a genus of purified antigens. Claim 12 still broadens the scope of claim 9 from which

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it depends. Amendment of claim 9 to recite the various embodiments of claim 12, could obviate this objection.

20. The rejection of claims 2-3, 10, 11, 22, 23 and 52 rejected under 35 U.S.C. 112, first paragraph (Deposit Requirement) is traversed on the grounds that the novel strains have been Deposited in a Budapest Treaty recognized depository and are described in the instant Specification on pages 2-3.

21. It is the position of the examiner while the accession numbers and information is listed in the instant Specification at pages 2-3, a statement that restrictions to access to these strains and species would be removed upon granting of a patent has not made, either in the instant Specification, nor in Applicant's Remarks.

One of the critical conditions of Deposit is defined in 37 CFR 1.808 requires that the deposit of biological material be made under two conditions: (A) access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C. 122, and (B) with one exception, that all restrictions imposed by the depositor on the availability to the public of the deposited biological material be irrevocably removed upon the granting of the patent.

Upon making this statement, the rejection under 35 USC 112, first paragraph will be withdrawn.

22. The rejection of claims 9-12, 15-17, 19-20 under 35 U.S.C. 112, first paragraph (scope) is traversed on the grounds that: Claim 9 has been amended to remove the "fragment or fragments" limitation, thereby obviating these rejections as to the remaining claims.

23. It is the position of the examiner that while claim 9 has been amended but claim 12 still recites a combination of claim limitations that define the scope of the claim to include a "fragment or fragments" of the microorganisms, specifically through setting forth the phrase "crude antigen mixture or purified antigen, or antigens from the microorganism". Applicant in the Remarks section of to the First Office action on page 10, "Paragraph 14" stated that "claim 12 is within the scope of claim 9", thus the embodiments set forth in claim 12 are encompassed by claim 9. The scope of enablement for any cell lysate, crude antigen mixture or purified antigen or antigens of any of the microorganisms to function as a pharmaceutical composition has not been enabled. The scope of enablement is maintained for reasons of record and responses set forth herein.

24. The rejection of claims 19-23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reciting the phrase "prophylaxis of lactic acidosis in a vertebrate" when the administered composition comprises lactic acid producing bacteria defined by the compositions of claim 1 and claim 10, and are administered to prevent lactic acid acidosis, is

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traversed on the grounds that the “vaccine formulations/pharmaceutical compositions” do not comprise carbohydrate, and therefore “themselves cannot cause lactic acidosis”.

25. It is the position of the examiner that the compositions administered in the claimed methods of claim 19-23 are for the prophylaxis of lactic acidosis in a vertebrate, and the composition administered comprise lactic acid producing bacteria. What is administered and what the recited intended use of the methods step are confusing. The rejection over claims 1-18 has been obviated through removal of the phrase “for the prevention of lactic acidosis in a vertebrate”, but the method of preventing or treating lactic acidosis with any lactic acid producing bacterial microorganism of either claim 1 or 10 does not distinctly claim Applicant’s invention. At no time did the examiner state that the compositions comprised carbohydrates, but upon establishment of colonization of the administered microorganisms that produce lactic acid, when the vertebrate eats, the production of lactic acid and an acidosis condition would result. The recited intended use of the claimed methods steps and the preamble do not correlate one to the other; the claimed methods do not distinctly claim Applicant’s invention when the microorganisms that produce lactic acid are administered to prevent the production of lactic acid acidosis. Adding additional microorganisms that would produce additional lactic acid to a vertebrate that already has acidosis is contradictory to the claimed method that is to treat or prevent acidosis caused by build up of lactic acid produced by microorganisms.

26. The rejection of claims 9-12,15-17,19-20 under 35 U.S.C. 112, second paragraph for reciting the term “fragment or fragments”, is traversed on the grounds that these claim limitations have been removed from the independent claims, thus obviating the rejection.

27. It is the position of the examiner that in light of claim 12 still reciting a combination of claim limitations that reads on the phrase “fragment or fragments” through the recitation of “crude antigen mixture or purified antigen or antigens from the microorganism.”, and claim 12 depending from independent claim 9, the scope of claim 9 including the species recited in claim 12 and all claims dependent from claim 9, the invention still reads on compositions that contain a fragment or fragments of the recited microorganisms.

28. The rejection of claims 1-3,9-11,23 and 52, as previously applied to claims 3, 11, 23 and 52, under 35 U.S.C. 112, second paragraph, for setting apart claim limitations in brackets, is traversed on the grounds that additional information has been inserted in the parentheses to clarify the meaning.

29. It is the position of the examiner that the presence of the parentheses is still unclear, because the information in the parentheses, aka brackets, is not positively recited in the claims, and appears to be set apart from the rest of the recited claim limitations. It is not clear whether the brackets (parentheses) define a suggested species within the scope of the claims, analogous to the phrase “such as” or whether the brackets are intended to define the species of invention. The claims are still unclear. Removal of the brackets (parentheses) to define positively recited claim limitations in relation to all of the other claim limitations could obviate this rejection.

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30. The rejection of claim 1,8-9,12, 16, 18, 19 and 21 under 35 U.S.C. 102(b) as being anticipated by Leer et al (WO97/14802) is traversed on the grounds that the adhesion of Leer et al was obtained from *Lactobacillus fermentum*, and is not a *Clostridium* microorganism

31. It is the position of the examiner that *Lactobacillus fermentum* is a lactic acid bacterial isolate that is only like *Clostridium* through binding to the same mucosal receptor as the *Clostridium* isolates tested. The reference still anticipates the instantly claimed invention in so far as *Lactobacillus fermentum* is a lactic acid bacterial isolate that is recited in claims 1-3, 8-12, 16,18-19 and 21. The *L. fermentum* bacteria (see page 10, lines 5-40) comprises a protein antigen that is able to inhibit colonization of another bacterial pathogen and therefore serves to prevent or therapeutically act as a vaccine, and an immune response (see page 16, lines 18-24) was induced to the protein antigen that is present in *L.fermentum* 104R bacteria. The reference still anticipates the instantly claimed compositions and methods that include any lactic acid producing bacterial isolate that would serve as a vaccine composition or a purified antigen from the lactic acid producing isolate that would serve to treat or prevent a condition associated therewith. The rejection is maintained for reasons of record in paper number 12204, paragraph 37 and responses to arguments above.

32. The rejection of claims 1-2,8-10, 12. 15-22 under 35 U.S.C. 102(b) as being anticipated by Rowe (WO99/00136, publication date January 7, 1999), is traversed on the grounds that:

h. Claims 1-2, 9 and 10 have been amended to recite particular species and/or strains of *Bacteroides*, *Selenomonas* and *Streptococcus* microorganism and therefore can not anticipate the instantly amended claims.

33. It is the position of the examiner that among the strains disclosed in WO99' are lactic acid producing isolates, as well as claims 1-2 recites a genus of *Enterococcus* species, and not

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any particular deposited strains or species as Applicant asserts; these embodiments are disclosed by WO99' and anticipate the instantly claimed invention.

New Grounds of Objection/Rejection

Claim Objections

2. Claims 1-3,5,8-12,15-23 and 52 are objected to because of the following informalities:

3. Claims 1-3,5,8-12,15-23 and 52 set forth a combination of claim limitations that are not consistent throughout the claim. For example: two different phrases are recited in claim 1:

"Bacteroides isolate LAB07 (Accession number :NM00/12636) is recited on lines 6-7 , and "Streptococcus bovis (strain:SbR1) (Accession number NM99/04455) on lines 9-10.

The Bacteroides isolated strain is set forth without brackets and the Streptococcus bovis strain is set apart from the genus/species name in brackets. For the specific species is to be positively recited in the claim, and not just a suggested example of what is encompassed by the scope of the claim, the strains and species should be set forth as shown for the Bacteroides isolate, without brackets. This type of inconsistency is present in all of the pending claims. Clarification is requested.

4. Claims 1-3, 9-11, 22-23 and 52 set forth an improper Markush Group format which recites the term "and" more than once: ie.: A, B and C and D and E. The term "and" should be recited only once: A, B, C, D and E. This rejection could be obviated through amendment of the claim to recite the term "and" only once when defining the species presented in Markush format. If combinations of two different microorganisms are intended, then a phrase to define the species directed to a combination should be defined by an introductory phrase ----the combination of A with B-----, or an equivalent phrase for which the instant Specification provides original descriptive support.

5. Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

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claim(s) in independent form. Claim 12 depends from claim 9 and is broader in scope as the claim encompasses not only the microorganisms of claim 9, but attenuated cells, cell lysates, crude antigen mixtures, purified antigens, and antigens from the microorganisms.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

34. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 recites “wherein the microorganism is provide as” “cell lysate, crude antigen mixture or purified antigen or antigens from the microorganism”. A microorganism is made of many different parts and proteins, but the individual parts or proteins is NOT the microorganism. According to Stedmann’s Medical dictionary, the term “microorganism” is : A microscopic organism (plant or animal). A cell lysate, crude antigen mixture or purified antigen or antigens is not a microorganism. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term “cell lysate, crude antigen mixture or purified antigen or antigens” in claim 12 is used by the claim to mean “microorganism”, while the accepted meaning is “microscopic plant or animal.” The term is indefinite because the specification does not clearly redefine the term.

Claim Rejections - 35 USC § 102

6. Claims 1, 9, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Vedamuthu et al (US Pat. 4,382,097).

Vedamuthu et al disclose a composition of living cells that are non-slime, lactic acid producing bacteria, which include *Streptococcus lactis*, *S. cremoris*, *S. thermophilus*, *Lactobacillus bulgaricus*, *L. acidophilus*, *L. lactis* (see col. 3, lines 5-16). The disclosed mixture of non-slime, lactic acid producing strain of bacteria were combine with milk or yogurt products, a type of pharmaceutically acceptable carrier and therefore anticipates the instantly claimed invention.

7. Claims 1-2, 9,10, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Cheng et al (US Pat. 5,939,303).

Cheng et al disclose a composition of a purified antigen and/or lyophilized living cells (see Table 1, col. 22, lines 23-26) of *Selenomonas ruminantium* or *Prevotella* spp. (see col. 3, lines 1-11; col. 4, lines 7-22) and were combined with animal feed, or drinking water (col. 4, lines 21-22, 29-33, and 39-40), a type of pharmaceutically acceptable carrier. Cheng et al anticipates the instantly claimed invention.

8. Claims 1,5, 9-10, 12, 19-20, 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawai et al (US Pat. 4,579,733 or US Pat. 4,710,379 or US Pat. 4,746,512).

Kawai et al disclose a pharmaceutical composition that comprises a mixture of bacterial strains and species containing either living or dead cells of *Streptococcus equines* (see '733

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claims 1-3 or '379, claims 1-2, or '512, claims 1-2). The disclosed mixture of non-slime, lactic acid producing strain of bacteria were combine with milk or yogurt products, a type of pharmaceutically acceptable carrier and therefore anticipates the instantly claimed invention.

Conclusion

1. This is a non-final action.
2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
3. Pier et al (US Pat. 5,055,455(col. 3, lines 12-32), US Pat. 5,980,910, and US Pat. 6,743,431) disclose a vaccine and pharmaceutical composition that comprises a bacterial adhesin that was isolated from a pathogenic strain of Staphylococcus epidermidis slime.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
October 18, 2004


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